IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT BLUEFIELD

TRANSCRIPT OF PROCEEDINGS

THE CITY OF HUNTINGTON, Plaintiff, vs. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	:	CIVIL ACTION NO. 3:17-cv-01362
CABELL COUNTY COMMISSION, Plaintiff, vs. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	:	CIVIL ACTION NO. 3:17-cv-01665

VIDEO PRE-TRIAL CONFERENCE

BEFORE THE HONORABLE DAVID A. FABER
SENIOR UNITED STATES DISTRICT JUDGE

FEBRUARY 9, 2021

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P R O C E E D I N G S

THE COURT: I assume we're ready to go.

A couple things. We have a very limited time this morning. I apologize for that. I'm going to try to expedite this by minimizing the time that I stick my nose in it and take the attorneys off their argument. So we'll try to move as fast as we can keeping in mind the limited amount of time.

We have a court reporter working from a remote location. So when you talk, please identify yourself so she can keep the record straight.

The first thing on the plate is the defendants' motion for summary judgment based on the statute of limitations.

And I have down Ms. Hardin for the defendants and Mr. Majestro for the plaintiffs. If that's wrong, please let me know.

If it's correct, Ms. Hardin, you may go forward.

MS. HARDIN: Good morning, Your Honor. Can you see and hear me?

THE COURT: Yes, I can.

MS. HARDIN: Great. Thank you.

I'm Ashley Hardin from Williams & Connolly on behalf of the defendants, Your Honor. And I will be presenting the defendants' motion for partial summary judgment on the statute of limitations.

Your Honor, there is a one-year statute of limitations that governs public nuisance claims in West Virginia. These plaintiffs have admitted that their claims accrued before May of 2015.

And, thus, by a straightforward application of the rule that applies to the triggering of the statute of limitations in nuisance cases, a rule that has been on the books in West Virginia since 1895, all the plaintiffs' claims that accrued outside of the one-year statutory period are time-barred.

THE COURT: Ms. Hardin, excuse me. Isn't there a question here as to whether the statute even applies in a case like this?

MS. HARDIN: The plaintiffs have raised the question about whether the statute applies, but there really is no question about that, Your Honor. As I said, that's been the, that's been the rule of when and how you apply the statute of limitations in a public nuisance case since at least 1895, then restated by the Supreme Court in West Virginia more than once, and as recently as 2003 in the *Taylor* vs. *Culloden Public Service District* case, Your Honor. What is typically difficult -- the reason this is actually quite straightforward here, Your Honor.

So, as I was saying, plaintiffs filed suit, City of Huntington in January of 2017, Cabell County in March of 2017. And, so, through the straightforward application of

that general rule, Your Honor, any claims that they have based on conduct that occurred before January or March of 2016 respectively are time-barred.

And the reason it's easy here, Your Honor, is because what would normally be difficult at this stage at summary judgment on statute of limitations would be a dispute of facts.

We'd be debating whether or not the plaintiffs knew of their claims, when they knew it, what they should have known, and when they should have known it. And here --

THE COURT: How do you get around the *Kermit Lumber* case, Ms. Hardin? If I understand it, it held that the statute does not begin to run in a nuisance case until the nuisance is abated. And it hasn't -- it hasn't been abated here, has it?

MS. HARDIN: Well, we do think -- we don't, number one, think there's ever been a nuisance, Your Honor. But nuisance-causing conduct is what we look to see whether that has been abated. And I believe that the plaintiffs before this Court in 2017 told you that the defendants are doing their jobs now. But the *Kermit Lumber* case, Your Honor, is an exception to the general rule.

So let me state the general rule first. And then I'll explain why *Kermit Lumber* isn't the case that we look to.

The general rule is set forth as long ago, as I said,

as 1895 in the *Henry* vs. *Ohio River* case and again, as I said, set forth again in the *Taylor* case and many cases in between.

And those cases set forth the general rule for when we apply and how we apply the statute of limitations in a continuing tort case, a continuing public nuisance case.

And I think the nomenclature gets a little bit confusing, Your Honor. West Virginia calls those temporary nuisances. But temporary just means on-going. So those cases where the conduct is alleged to have been on-going for a long time, but also alleged to be continuing within the statutory period. And that rule, as I said, set forth as long ago as 1895 is this. I'm quoting from the *Henry* vs. *Ohio River* case.

And it says that the general rule as to nuisance is that every continuance from day-to-day is a new nuisance for which a fresh action lies, so that though action for the original nuisance be barred, damages are recoverable for the statutory period for injuries within it.

That's the general rule set forth many times by the West Virginia Supreme Court of Appeals.

And, so, if the defendants commit tortious conduct today, engages in nuisance-causing conduct today, then a fresh action, a fresh cause of action is triggered today for public nuisance and a fresh statute of limitations is

triggered --

THE COURT: I don't mean to interrupt you. I understand that. But that is inconsistent with the *Kermit Lumber* case. And you have to tell me why this case does not fall within the rule of *Kermit Lumber*.

MS. HARDIN: Certainly, Your Honor.

THE COURT: Okay.

MS. HARDIN: We do not believe -- sure. First of all, we don't believe that *Kermit Lumber* is inconsistent with that in any way.

Kermit Lumber is an exception to the general rule. *Kermit Lumber* notes the general rule, notes that the continuing tort doctrine applies based on continuing conduct and not simply continuing ill effects from previous conduct.

But what -- and, and, importantly, because I think plaintiffs are going to tell you that no statute of limitations applies at all to a claim to abate a public nuisance. *Kermit Lumber* does not hold that.

Under the heading "Is there a relevant statute of limitations," the Supreme Court in *Kermit Lumber* says, yes, there is. And it's one year for public nuisance claims.

And then what *Kermit Lumber* -- the Court in *Kermit Lumber* went on to do was to hold that there is an exception -- they, they noted a special accrual rule for a very particular and narrow class of cases. And that case

dealt with a hazardous waste contamination and a business site remediation.

And the *Kermit Lumber* case says we are -- the general rule, we acknowledge it. It's been on the books. That's what we typically apply in a public nuisance case, but here we find that rule unworkable because even though the conduct had occurred long ago, the contaminants were continuing to leach into the soil.

And for that very narrow class of cases, the Court said even though the conduct occurred long ago, we're going to hold that the one-year statute of limitations does not accrue while the contaminants remain in the ground.

But the reason that's the exception and the reason that is not the rule that applies here, Your Honor, is -- and the Supreme Court tells us -- they were -- they expressly say in *Kermit Lumber* that the special rule is limited and another set of facts might require a different rule.

And it's not even a rule that's applicable to all environmental cases, Your Honor. It is a very particular rule that applies to business site remediation of a hazardous waste.

No court in West Virginia has ever applied *Kermit Lumber* outside of that very particular set of circumstances. And we submit, Your Honor, that this Federal Court sitting in diversity under *Erie* cannot be the first one to do so.

So that's an exception. It's not the general rule and it doesn't apply here. And it doesn't hold that no statute of limitations applies to a public nuisance claim.

We are under the general rule, the *Henry* vs. *Ohio* rule, the *Taylor* rule that says new conduct triggers a fresh statute of limitations. And the continuing tort doctrine doesn't save the old claims.

So if the plaintiffs here -- the application here is that if the plaintiffs have evidence that the distributors shipped too many pills, is what they accuse us of doing, from January, 2016, to the present, then they may maintain a cause of action at least for purposes of the statute of limitations for those claims.

What they may not do is base a liability finding on the defendants' conduct that occurred in 1996 or 2006 or 2010. The plaintiffs admit they have been on notice of their claims they admit since -- as long ago as 2012.

So, as I said at the beginning, there are no factual disputes here. Plaintiffs have taken the position that the facts are irrelevant. And they hang their hat on one legal argument that there's no statute of limitations.

But the difficulty for the plaintiffs is that they have admitted that their claims accrued before May of 2015. They admitted --

THE COURT: I'm sorry to interrupt you, Ms.

Hardin, but in the interest of time, I think I understand where you're coming from. I read your brief. And I want to give the other side an opportunity and I want to get to the other issues here.

So if you can just -- if there are any specific points you haven't made that you want to get across, get through them and then we'll move on. I wish I could give you more time, but I can't.

MS. HARDIN: I understand, Your Honor. I appreciate it.

I will make one point before I let you move on to the plaintiffs, Your Honor. And that is what I think you're going to hear is the centerpiece of the plaintiffs' argument. They are going to tell you that no statute of limitations applies in this case because they seek equitable relief.

And it is true that we have a dispute about the proper label that applies to the big pot of money that they want to, that they want to seek here. They want money. There's no dispute about that. They want a lot of it.

But -- and we will, we will debate the proper label for, for that at another time and place, Your Honor. That's teed up before Your Honor in another set of motions and the Supreme Court's going to take it up later this month.

But whatever label we end up putting on that relief

does not affect the running of the statute of limitations because the question on statute of limitations is not what label we put on the relief, but for what time period may they seek the relief.

If there is a present-day nuisance, they could have sought to enjoin that conduct. That is abatement. That is all abatement has ever meant in the State of West Virginia, or they could have sought damages within the statutory period.

So the question is: When can they seek the relief? They could have sought an injunction. They could have sought abatement. They could have sought damages, one or the other. It doesn't matter.

The question is: When did the conduct occur? How does the statute of limitations apply? And we look to *Taylor*. We look to *Henry*. And here is a straightforward, simple, easy application, Your Honor.

So for that reason, we submit that Your Honor should grant partial summary judgment to the defendants on the statute of limitations.

THE COURT: Thank you, Ms. Hardin.

Mr. Majestro, are you the one to respond here?

MR. MAJESTRO: Yes, Your Honor. Anthony Majestro for the plaintiffs.

Can everyone hear me okay?

THE COURT: Yes, I can hear you. Go ahead.

MR. MAJESTRO: That's all that matters.

Your Honor, defendants confuse the remedies in a public and a private nuisance claim. In a public nuisance claim, the government is acting to protect health and safety of the public, and the focus is on the conditions that endanger health and human safety; contrast with a private nuisance claim where plaintiffs seek damages where the focus is on the acts of the defendants of the damages incurred by the plaintiff.

In essence, what the defendants want you to do is apply those private damage -- private nuisance rules to a public nuisance case.

The second point -- general point I want to make, Your Honor, is that defendants, what they're doing, as, as Ms. Hardin admitted, is they're trying to seek the abatement remedy to acts that occurred prior to January and February of 2016.

But I want to explain -- show you a little bit about what we're talking about here.

Can we pull up Slide Number 1? I have a couple of slides. We'll see if they work.

THE COURT: I can't see it, Mr. Majestro.

MR. MAJESTRO: All right. Well, let's skip that then. I'll just tell you what they say.

So what the slides would show, Your Honor, is that between 1997 and 2019, 2.8 billion milligrams of morphine, or the equivalent of that, were distributed into Cabell County, 2.8 billion.

Now, of that, 2.5 billion were distributed prior to 2016. So the vast majority of -- at least in terms of this measure -- there are lots of different measures that we'll -- when we get into the data end in this case. I'm just picking this one because it's illustrative. But there is a large chunk of this, of the conduct that occurred prior to 2016.

Now, however, the impact of those, of that conduct, like the hazardous waste leaching into the water, stayed past the time that, that the defendants distributed the charts.

For example, in the deaths -- if we just take the deaths that happened, in the, in the three-year period from 2016 to 2018, there were 324 opioid deaths in Cabell County in Huntington. But in the ten years prior to that, there were 327, so just three less deaths occurring over a three-year period than over a ten-year period.

So what that is evidence of -- and our abatement experts and causation experts will establish that the, that the conduct of the defendants that occurred prior to 2016 caused a nuisance, that its effects continued to harm the

health and safety of Cabell County.

So those are essentially the material facts that are necessary to decide this, this motion. That -- this nuisance existed and that, that it's continued and not abated.

Now, Ms. Hardin is right. We have two arguments.

The first is that there's no statute of limitations on a claim -- on an equitable claim for abatement.

The law is clear. There is no statute of limitations for claims seeking equitable relief. Now, in CT1 in his August, 26th, 2019 hearing Judge Polster explained in a public nuisance case, the harmed party can, when appropriate, abate the public nuisance or ask the Court for the right to do so and then seek compensation for the cost of abating the nuisance.

This compensation is equitable in nature. The goal is not to compensate the harmed party for the harm already caused by the nuisance. This would be an award of damages. Instead, an abatement remedy is intended to compensate the plaintiff for the cost of rectifying that nuisance going forward.

The West Virginia Mass Litigation Panel accepted this, this statement of the general common law as applied to West Virginia law in, in its September 4th, 2019, decision.

Now, Ms. Hardin is right. The Supreme Court may

address this issue later this month. And they don't seriously -- they don't seriously contend -- they don't seriously quibble with our arguments as to why our claims are equitable versus not, not equitable.

And I would refer the Court to our briefing on that issue so we won't -- since she didn't address it, I won't either.

But essentially what those cases show is that the payment of money is not determinative and that equity is not limited to injunctive relief.

And for the Court's edification, we've cited the case law supporting that on Page 7 to 8 of our reply in support of the motion to strike which was incorporated by reference into this response which is Doc 286. And then additionally there are additional cases cited on Pages 9 to 10 of that same Document 286.

Essentially, though, as the Supreme Court noted in *Cashcall* vs. *Morrisey*, equity is flexible. Courts have broad powers to fashion equitable relief. And the Court's equitable powers assume even broader, more flexible character when the public interest is involved in a proceeding in order to secure complete justice. And for that, they cite the U.S. Supreme Court's opinion in *Porter* vs. *Warner Holding*.

Now, essentially -- so that -- so before we even get to

whether this is damages or equity, the -- or when the statute of limitations accrues, all of that discussion Ms. Hardin explained, that is all irrelevant because this is an equitable abatement claim to which no statute of limitations applies.

The second argument, and that is, that is *Kermit Lumber*. You know, I think that the -- that it's -- that Ms. Hardin completely misstates the, the import of what *Kermit Lumber* is talking about.

The *Kermit Lumber* rule is not that there's no statute of limitations on unabated public nuisance cases. It is that the statute of limitations, when there is a danger to health and safety in a public nuisance case, does not begin to run until the nuisance is abated.

Now, this is a fairly common sense ruling. When the public nuisance doctrine, which its entire intent is to protect health, safety, environment exists, that a -- when a government is trying to protect that health and safety by seeking abatement of a, a problem to that health and safety, any other rule would be, would be extremely dangerous to the health and safety. So that, that -- we'll start there.

Second, *Kermit* applies to a temporary nuisance that is abatable and unabated. There's not any distinction that we have created a sufficient record to establish to go forward on that claim. The plaintiffs' expert reports alone which

were filed in support of all of our *Daubert* motions are sufficient for that.

The next point, *Kermit* applies whether or not the damages are compensatory or equitable. *Kermit Lumber* -- in *Kermit Lumber* the plaintiffs explicitly sought compensatory and punitive damages. So it's clear that even if Ms. Hardin is right and that our claims are not equitable, the *Kermit Lumber* rule still applies.

Third, the discovery of the defendants' conduct is not applicable under *Kermit Lumber*. Notably, in *Kermit Lumber* the Supreme Court wasn't troubled by either the fact that the state first learned of the contamination and Kermit Lumber's actions in 1987 and a criminal conviction in 1988.

So '87 - '88 was when the state learned about it, but the lawsuit was not filed until 1995. The Supreme Court didn't even discuss that, that -- the fact that there was some discovery of this more than a year back.

Fourth, *Kermit Lumber* made clear for statute of limitations purposes that the focus of a public nuisance abatement action involving health and safety is the condition, not the defendant's conduct.

The, the quote that Ms. Hardin has in their brief, they leave out some passages that are, that are important.

The first is the *Kermit Lumber* court expressly noted the object of a public nuisance action is to abate or stop

the harm to the public health, safety, and environment which will continue until the hazardous waste is removed. That's at Footnote 29 of the opinion.

The Court also noted in the paragraph that's not quoted in defendants' reply that the -- the part that is ellipsis-ed out, the Court noted that the focus of a governmental public nuisance action is, quote, the continuing harm to the public interest rather than when the acts of the persons in placing the hazardous waste in the soil stopped, clearly distinguishing between conduct and condition. When it's a public nuisance hurting the health and safety of the public, the focus is on the condition, not the conduct.

Now, the Court also noted that a different rule -- in a, in a sentence ellipsis-ed out by the defendants that a different rule applies in private nuisance cases, and that those cases are, quote, less than helpful because they focus on individual harms rather than harms to the public, health, safety, and environment.

So we have -- our slides are working. So this is the, the -- in yellow is the --

Can you see it on the screen, Your Honor?

THE COURT: Yeah, I can see it now.

MR. MAJESTRO: Okay. So the defendants' quote is the highlighted in yellow part. The bolded part is the rest

of the story from the Court.

And, you know, that, that -- essentially by extracting out the focus on conditions, they totally distort the meaning of the case.

Now, the cases cited by the defendants are cases brought by private parties sounding in private nuisance or other non-nuisance theories, precisely the kind of cases *Kermit Lumber* noted were, quote, less than helpful because they focused on private damages rather than the public interest in abating the harm.

So this general rule that the defendants --

We can get rid of the slides now. We're done.

This general rule that the defendants speak of is a rule that's applicable in non-public nuisance cases and in cases where there is not an existing harm to health, safety, and environment.

Now, they, they rely a lot on *Taylor*. *Taylor* is distinguishable.

First, it's a private nuisance case where a property owner was seeking damages for injury to his property. We should contrast that with *Taylor* with *Kermit Lumber* where the Court expressly noted that private nuisances are different, and noted that the focus is not on defending parties' interest in continuing the nuisance but on the type of harm suffered.

Taylor did not overrule *Kermit*. In fact, *Taylor* recognized that, that *Kermit* provided a special benefit for, you know, a public nuisance case.

The Court found it unnecessary to reach that because the plaintiff in *Taylor* was able to recover all of his damages in his private nuisance action which were within the statute of limitations under the rule set forth in *Taylor*.

Now, these rulings are consistent with how other courts have, have viewed West Virginia law and the law generally. Judge Polster came to the same conclusion and upheld that no statute of limitations applied to an unabated public nuisance under Ohio law. The trial court in Alabama in the opioid cases came to a similar holding.

But Ms. Hardin says no West Virginia Court has ever held -- has ever accepted the argument that we made. That is patently untrue.

In West -- in interpreting West Virginia law, Judge Hummel in Marshall County and the West Virginia Mass Litigation Panel which upheld Judge Hummel's rulings both found -- applied the *Kermit Lumber* rule and found no statute of limitations begin to run on public nuisance claims in the opioid litigation because the, the nuisance is unabated.

Now, in both of those cases, the West Virginia Supreme Court unanimously denied writs of prohibition seeking to challenge the trial court decisions.

Unlike the holdings the Court currently considered, it's not like the Court is ignoring this litigation. With respect to those rulings from Judge Hummel and the Mass Litigation Panel, the Supreme Court unanimously denied the writs.

Finally, in this very case, Special Master Wilkes denied a motion to compel by the defendants where the plaintiffs were, were objecting to respond to discovery to identify the date and manner in which (video inaudible) diverted. They wanted to do discovery into this discovery rule issue. We objected, said the discovery is burdensome and irrelevant.

And what the Court -- what Judge Wilkes said was West Virginia law provides the statute of limitations on nuisance actions does not begin to run until the nuisance is abated in this very case, citing *Kermit Lumber* and the ruling that the defendants did not challenge to this Court.

So in total, eight West Virginia jurists sitting on four trial and appellate courts have rejected these arguments that *Kermit Lumber* doesn't govern.

Now, defendants argue that this Court should conservatively interpret *Kermit Lumber*. I would just say that under the *Erie* doctrine, this Court's task is to predict how the Supreme Court of Appeals would rule. The result ought to be the same in Federal Court as it is in

State Court. That's the whole basis for, for *Erie*.

So -- and we've cited some case law on, on how the Court does this in one of our, in one of our nuisance responses, Doc 1077, Page 11, Footnote 2.

And, essentially, while not binding, these West Virginia Circuit Court decisions provide persuasive guidance to a Federal Court sitting in diversity, particularly where they're uniform as here.

Also, when there's no -- and as the U.S. Supreme Court even said in the *Estate of Bosch* case, there will be no decision by the state's highest court that the federal authorities must apply what they find to be the state law after giving proper regard to relevant rulings of courts of the state.

So, essentially, we believe all of these decisions interpreting a very straightforward case, *Kermit Lumber*, should be applied by this Court as a matter of, of diversity.

We're not asking for anything more than this Court to apply *Kermit Lumber's* reasoning and the Court's express language. This is the Court's express language in *Kermit Lumber*:

"Thus, until such harm to public health and safety is abated, the public nuisance is continuing and the statute of limitations does not begin to accrue."

Now, the last point I want to discuss is the similarity between the opioid epidemic and environmental contamination because that's, that's the only hook the defendants really have on *Kermit Lumber*.

And that is that environmental contamination requires some special rule. And they're focusing on that language that, that we had on the screen before. And other public nuisances -- other nuisances may be different.

And -- but I, but I think when you look at what happened in this case that the, the basis for *Kermit Lumber's* ruling, a concern over the protection of health and safety, is equally applicable with the opioid epidemic.

All of the harms we have, the death, addiction, damage to children, all those things are concerns that touch on health and safety.

Opioid addiction is essentially like the hazardous waste in *Kermit Lumber* because once placed in -- once you place those addicts in the community, they continue to cause harm. And until you remediate the harm that is caused by all these pills that were sent into those communities, the harm is going to continue.

Those numbers I started with are evidence that that harm continues well past the stopping of the shipping of particular pills.

Now, --

THE COURT: I'm going to cut you off here pretty soon, Mr. Majestro. So --

MR. MAJESTRO: I've got -- I just have one, one more point.

THE COURT: Okay.

MR. MAJESTRO: And that is -- so, so what does the Court mean when they say other nuisances may be different, other public nuisances? Let's talk about some other nuisances.

Contrast a business that attracts excess traffic in a residential area. That is a -- may be a public nuisance, but it's not a nuisance that impacts health and safety. A hog pen which has smells also may not impact health and safety, or a business that's causing excess noise would be another example. Those are all examples of nuisances that are not implicated by health and safety. So maybe the *Taylor/Lumber* rule applies in that kind of case.

But in a case like this case, a case like contamination where you have arsenic leaching into the water like in *Kermit Lumber* or maybe a case involving infectious diseases, those are cases that trigger health and safety that, that -- where the purpose behind a public nuisance abatement action is met by not having the statute of limitations run until the nuisance is abated.

THE COURT: Okay. Thank you.

Ms. Hardin, --

MS. HARDIN: May I respond, Your Honor?

THE COURT: Yes, you may quickly, Ms. Hardin.

MS. HARDIN: Yes.

Taylor, Your Honor, plaintiffs say it doesn't apply because it's a private nuisance claim. The Supreme Court of West Virginia says in the *Taylor* opinion that that doesn't matter. They expressly consider whether the plaintiffs needed to have asserted a public nuisance claim in order to take advantage of the general rule, the general continuing tort rule, and the Supreme Court said, no, you don't.

And any suggestion that that case involved somekind of outdated conduct is belied by the opinion where the Supreme Court says the dumping of raw sewage into the Indian Creek Fork continues even unto this day.

And the Supreme Court was also very clear to, to make the point that these plaintiffs could have asserted a public nuisance claim because the issue was the pollution of state waters. So the Supreme Court has told us the distinction between private and public doesn't matter for the general rule.

In *Kermit Lumber*, this is not a distinction or a law that the defendants are putting on *Kermit Lumber*, Your Honor. This is what the Supreme Court itself tells us we are to do and how to apply *Kermit Lumber*. It's Footnote 29.

It says, "We make clear that we are concerned with a public nuisance involving hazardous waste which is in the soil and leaching into a river. A different public nuisance or a different private nuisance might make a difference."

But we -- that is limited to its facts. And the suggestion that eight other West Virginia courts have held otherwise, there's been one ruling from a trial court that addressed this in one paragraph in a submitted order that was written verbatim and signed word-for-word by the plaintiffs' lawyer.

Judge Polster has never taken up the issue of the statute of limitations in West Virginia. And the fact that the Supreme Court denied the writ is, of course, no indictment of the arguments that are made in the writ.

And, lastly, I'll just address this notion, Your Honor, that this case is factually similar to the *Kermit Lumber* case.

Nothing could be further from the truth. The hyperbole and the rhetoric from plaintiffs' side about the contaminants leaching into the soil is, is not -- does not make this case like *Kermit Lumber*.

Defendants ship -- wholesale distributors is what defendants are. We ship prescription drugs that are FDA approved and we're licensed by the DEA and registered by the state to do so.

It doesn't matter how many we ship. We could have shipped too many just as the plaintiffs say. And every single one of them sits under lock and key at the pharmacy. And they can't get out into society unless a whole host of other DEA registered and state licensed entities write prescriptions and dispense the drugs.

So there is no pill spill. We do not, we do not drop these pills into the town square. We certainly do not do as Mr. Majestro said, place addicts into the community in the way that people dump chemicals into the ground. There are no factual similarities.

That case is limited, *Kermit Lumber*, not only, as I said, to any environmental case -- and there is nothing in Footnote 29 that says *Kermit Lumber* applies to health and safety cases. That is not the ruling of *Kermit Lumber*. It is a narrow exception.

The general rule of *Taylor* and *Henry* -- again, this is a rule that's been in effect, Your Honor, in West Virginia for more than 120 years. And the application here is straightforward.

These plaintiffs want to come in and admit for one purpose that their claims accrued before May of 2015. They want to avoid the application of one unfavorable statute, the non-party fault statute, but they want to have their cake and eat it too because that -- they borrow trouble for

themselves on the statute of limitations and they want to try to avoid both by saying that there's no statute of limitations in Virginia -- excuse me -- in West Virginia. And that is not accurate, Your Honor. There is nothing in the case law that suggests that that is the case.

They've admitted that their claims accrued before May of 2015. That is a stunning admission, Your Honor. They knew of their claims since before -- as long ago as 2012 and they want this Court to hold that there are no consequences to that admission. And that is not the law in West Virginia.

There is a one-year statute. They admit their claims accrued in May of 2015. And, therefore, claims outside the one-year statutory period are time-barred, Your Honor.

THE COURT: Okay. Thank you.

MS. HARDIN: Thank you.

THE COURT: Let's move on to the next area here. We want to cover the plaintiffs' motion to adopt the MDL Court's ruling on distributors' duties under the Controlled Substances Act -- that's their law of the case argument -- and also the plaintiffs' motion for summary judgment on the distributors' duties under the Controlled Substances Act.

Mr. Hester, are you going to carry the ball for the defendants on this one?

MR. HESTER: Yes, I am, Your Honor. Thank you.

THE COURT: You may proceed.

MR. HESTER: Okay.

THE COURT: I'm sorry. I misspoke. I get things backwards. I know which side you're on, Mr. Hester. Go ahead.

MR. HESTER: Thank you, Your Honor.

THE COURT: Go ahead, please.

Oh, I'm sorry. It's the plaintiffs' motion and I've got Ms. Kearse and Mr. Farrell down for the plaintiffs.

Am I straight now?

Mr. Farrell, are you going to go forward or Ms. Kearse?

MS. KEARSE: Your Honor, this is Anne Kearse for the plaintiffs. Andrea Bierstein is also with us as well and will address the Court with Mr. Farrell.

THE COURT: Okay.

MS. KEARSE: Your Honor, you're right. Plaintiffs did file two motions in regard to the Controlled Substances Act asking the Court to determine as a matter of law the legal obligations defendant distributors have under the CSA.

The plaintiffs filed one motion to adopt the Multi-District Litigation Court's order regarding the CSA. And that's Judge Polster's order that was issued on August 19th, 2019.

And plaintiffs subsequently filed a motion for partial summary judgment concerning the defendants' statutory and

regulatory duties.

They're different means to the same end asking this Court to rule as a matter of law that the Controlled Substances Act, Section 1301, and those that follow require the defendants who are DEA registrants to identify suspicious orders of controlled substances, report the DEA -- to the DEA suspicious orders of controlled substances, and to decline to ship suspicious orders until and unless through due diligence the registrar can determine the order is not likely to be diverted into illegal channels.

I'm going to touch just briefly, Your Honor, on the MDL coordination proceedings and the law of the case. And then Mr. Farrell and Ms. Bierstein will touch on the substantive issues that should lead the Court to the same conclusions both under the CSA and under the West Virginia Controlled Substances Act.

Your Honor, the -- under the law, the case principles that, that you actually raised in the March 5th hearing about a year ago, the MDL Court presumptively (video inaudible) with respect to the common issues. And our briefs show that these are common issues that the Court should address. There were common issues in the MDL proceedings.

During our status conference, as you'll recall, you

told the, the parties that you intended to follow Judge Polster's ruling unless there was changed circumstances warranting their modification. And this decision was guided under the Fourth Circuit 1996 decision in *Royster*.

Under *Royster* and the guiding multi-state -- multi-district litigation principles, the MDL Court's rulings on common issues should be presumptively applied on remand. And as noted by the Court in *Royster* and also in the hearing, to upset the MDL's ruling would be an undermining of the purposes and usefulness of the transfer under 28, U.S.C., --

THE COURT: Let me interject here a minute.

It's my understanding that the law of the case doctrine only applies if it is the same specific case. Here you don't have that. You have a -- have rulings that Judge Polster made generally in the multi-district litigation if I understand them correctly.

So, technically, the law of the case doesn't apply and you're stuck with the argument that a similar rule should be applied here just to avoid confusion and so forth.

So you're on a little less firm ground than if, if he had made that ruling in this specific case, are you not?

MS. KEARSE: Your Honor, that's -- we do call the law of the case principles because the principles apply under multi-district litigation both within the, the complex

litigation manuals and writings of the Court's common issues in a multi-district litigation.

And, importantly, Your Honor, Judge Polster in his evidentiary order of December 26th, 2019, explained that the ruling did apply to all future MDL cases within his court that he was going to try.

But, additionally, as a general matter, as Your Honor just stated, these rulings apply to remanded cases tried by the transferor court --

THE COURT: In what context did, did he make that ruling? What claims was he, was he addressing and how is that consistent with the, the situation that confronts me right now?

MS. KEARSE: Your Honor, he was addressing all claims, including the public nuisance claim that was set for the first bellwether trial that was set and settled at the eve of trial with that.

But, importantly, Your Honor, these are presumptive. These are still discretionary. It's not necessarily binding. Judge Breyer in the District Court of the Northern District of California also had the same motions before him.

And what Judge Breyer said is that these should be used as springboards, that they should be given great weight in the decisions. But Judge Breyer also took an independent analysis to see if there was a change in circumstances or

whether the California law or Eleventh Circuit law actually had different findings there that would change circumstances.

And that's what we've asked the Court in our motion on the MDL proceeding is that if there's changed circumstances, then there would be a further review of that. And there's no relevant changed circumstances before your Court based on Fourth Circuit law with that either, what Judge Breyer used within the Ninth Circuit law and California law and using it as a springboard to look at his independent review of the case as well.

So we've set this motion up basically in a two-phase.

One, there is precedent to utilize the findings that Judge Polster made both in his order and subsequent evidentiary order extending it to the transferee and transferor court, but also for Your Honor to take an independent review of that, utilizing the presumptive nature of this ruling and the analysis that went into it that Mr. Farrell and Ms. Bierstein will address for Your Honor with that too.

So we've, we've presented it in two different fashions with that, Your Honor, but we do think it at least has great presumptive value to Your Honor on -- under the CSA claims that are just the same as here. There's no difference in the rule of law of the duties and obligations of the

defendants based on the CSA and the findings of Judge Polster in his MDL proceedings for the bellwether one trial. And, of course, as Your Honor knows, this is the bellwether two trial.

The Northern District of California case is also a bellwether case that will be proceeding to trial later this year.

THE COURT: Are you through?

MS. KEARSE: Yeah, I think, Your Honor, I think if we want to go ahead and have Mr. Farrell and Ms. Bierstein work through that as well.

But, again, our position is that Your Honor could use a law of the case principles and the multi-district guidance on transferee and transferor court rulings as precedent for adopting Judge Polster's ruling. But I'll turn it over to Mr. Farrell, Your Honor.

THE COURT: Maybe I ought to hear from Mr. Hester on this before I go on to, to the other motion that's related here.

So let me hear from you, Mr. Hester.

MR. HESTER: Thank you, Your Honor. Good morning. Timothy Hester, counsel for McKesson Corporation.

Your Honor, you have a --

THE COURT: I accused you of being a plaintiffs' lawyer again, Mr. Hester.

MR. HESTER: Well, I will be sure to inform my partners that I have the ability to switch sides.

(Laughter)

MR. HESTER: Your Honor, I, I think you have it just right when you stated the rule of law; that the law of the case doctrine does not apply unless orders are entered in the same case.

And as the Court pointed out, the order issued by Judge Polster was not in this case. It was in other cases that were before him in the MDL --

THE COURT: Well, --

MR. HESTER: -- and there is no exception.

THE COURT: Let me ask a question that's on my mind. I hope I can frame it properly.

How was the context in which Judge Polster made that ruling consistent or inconsistent with the situation that we have before us now? Was it addressing similar claims or different claims?

MR. HESTER: Well, Your Honor, my understanding is that he was -- he issued that order in the MDL proceeding in relation to cases that were still before him.

So the question, as I understand it, was whether his orders would apply to another case that was going to trial before him in Ohio.

But here he obviously did not enter these orders in

this case. And, so, the law of the case doctrine just is inapplicable here. He was, he was entering an order in the MDL proceeding in relation to cases that were still before him which is different from the situation we have here where cases have been transferred back for trial.

THE COURT: What claims were pending in that case, Mr. Hester, if you know, when the, when the ruling was made? Were they the same as the claims we have here or different if you know?

MR. HESTER: I, I don't know at a detailed level, Your Honor. My understanding is that they, that they included public nuisance claims. But, but I don't know specifically what the claims were. But there's two points I wanted to make.

First, that the law of the case doctrine doesn't apply because they were not entered in this case. His order was not entered in this case.

But, second, even on its own terms, that was a partial summary judgment ruling subject to reconsideration. And it's an interlocutory order. And it's well settled that the law of the case does not apply in that circumstance.

So Ms. Kearse made the point that the Court shouldn't apply literally the law of the case doctrine as I heard her. Rather, she was saying it should be presumptive or a springboard.

And I'm ready to address that, Your Honor, because there are some differences here. There are some things that have happened since Judge Polster's rulings.

There's evidence that would be presented to this Court that was not considered by Judge Polster in his order. And there's been a new development with DEA rule-making to add a no-ship requirement. That was a fact that was not before Judge Polster at the time he entered his order.

But there's also an important procedural difference here, Your Honor. Judge Polster was getting ready for a jury trial. So was Judge Breyer in his order in San Francisco.

Here we have a bench trial. It's unnecessary for the Court to be making a legal ruling on this issue. And as I can discuss in more detail, the facts that are going to come out at trial, the evidence bears on this legal question of the nature of this duty, what's the difference between a suspicious order and an order likely to be diverted. These are factual points on which the Court will hear evidence.

The Court will also hear evidence on the shifting positions that DEA took on this issue over time. And all of that evidentiary record informs the legal issue. And here we are in a bench trial. It's not necessary. It's not appropriate procedurally. It's not a proper Rule 56 motion. It's not properly framed as the law of the case.

But putting all that aside is a matter of the Court's discretion. It's not necessary at this early stage to be entering an order on this issue because the evidence is going to inform the resolution of this issue.

I'm happy to go on, Your Honor, but I, I suspect the plaintiffs are ready to go back on other parts of their argument.

THE COURT: Well, the point you just made, I'd like to hear what they have to say about that.

MR. FARRELL: Judge, this is Paul Farrell. I hope everybody can hear me.

THE COURT: Yeah, I can hear you.

MR. FARRELL: So I, I guess the, the best way for me to proceed is I want to provide a little bit of context so that we understand why it is that we're having this discussion at this point in time.

And I can say with absolute confidence that this legal issue is well-briefed and well-argued and well-known to all of the lawyers on this call.

When you look at the public nuisance --

THE COURT: Doesn't Mr. Hester make a good point based on the fact that this is a bench trial? And I, I want to -- it seems to me I ought to reserve this until I can place it in the specific context of the evidence. And then I can make a ruling on it and I don't have to be concerned

about confusing or misleading the jury. I can sort it out based on the fuller record that's before me at that time.

MR. FARRELL: I don't have any disagreement if that's the pathway that you wish to choose.

There is a ripple effect that will occur based upon what the legal duty is in the case. So let me be as brief as I can to provide context for you.

The, the -- public nuisance is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons. So there's no question that there's going to be underlying conduct that gives rise to the public nuisance.

The plaintiffs and the defendants are going to argue about whether that underlying conduct is governed by negligence, unreasonable interference, unlawful or intentional.

But, nonetheless, the, the issue as to what their duty is under the law is what we've been fighting about since the beginning of this litigation.

The statute was enacted in 1970. The C.F.R. provision was enacted in 1971. And if you'll recall, on June 21st, 2017, this same group of wonderful lawyers appeared before you to argue a motion to dismiss.

And at that point in time, we were arguing about the nature of that legal duty. That was the basis for the

argument on June 21st, 2017.

Nine days later on June 30th, 2017, the D.C. Circuit Court issued its ruling in *Masters*. Following that, what we have is Judge Polster making a ruling on the legal duty.

Then that issue was addressed by Judge Breyer in almost the exact same circumstances that we argued the law of the case. They argued that there was something different.

Judge Breyer's opinion goes through the analysis and says that we'll use it as a springboard, but makes an independent finding on the nature of the legal duty.

The only thing that's really changed since Judge Breyer's opinion is the onset of a new proposed rule-making by the DEA and the impact of that. And the plaintiffs argue that it means one thing and the defendants argue that it means another.

And, so, what we believe is that as West Virginia law has long recognized, the existence of a duty is a legal issue for the Court to determine. And what we're asking is for the Court to make a legal ruling on the nature of that duty along this sequence of procedural history.

Otherwise, what's going to happen is that we're going to be presenting to you experts on what the law is or is not which traditionally has not been something that the Court has entertained because as the Court has often held in litigation, this is for the Court to determine, not for the

jury.

So where we're at today is a motion for partial summary judgment on the nature of the duty, which I think is very fair to be in the breast of the Court. And if and when you make a ruling on it, then there will be a series of consequences on how this case proceeds.

MS. BIERSTEIN: If I could now, Your Honor, -- this is Andrea Bierstein and I wanted to jump in and comment on what Mr. Farrell just said and to second everything he said.

But I want to add some facts of context that may address the questions Your Honor was raising, and also address one of the points that Mr. Hester made.

So to begin with, when Judge Breyer issued his ruling in California, he had not yet determined whether it was going to be a bench trial or a jury trial. So that purported distinction is not in fact a distinction because Judge Breyer's ruling did not turn on that. As I said, he had not yet made that ruling.

The context in which Judge Polster issued this ruling was virtually identical to the context here. That is the argument that the plaintiffs made about why this issue mattered, how it set the framework because in Ohio, as in West Virginia, unlawful conduct is a predicate for nuisance.

And, so, the question was: Have the defendants behaved

unlawfully? And that's the more complicated question that was reserved for trial in Ohio. But the threshold question: Well, what is the law, what were they required to do, was exactly the same question in the same context for Judge Polster as it is before Your Honor.

And the reason is as Mr. Farrell suggested. It is a pure legal question. Whether -- once we know what the defendants' duties are under the law, at trial the parties can put in evidence to show they violated it, they didn't violate it, they were confused, they thought it was different, there were mitigating circumstances, the orders didn't look suspicious, whatever evidence they want to put in. But the basic legal duty sets the framework for what is at issue at trial.

And, so, the reason to decide it, it would be like going to trial without knowing, you know, what a public nuisance is. And, so, it, it sets the legal framework for that.

Another thing I wanted to point out to Your Honor was --

THE COURT: Let me ask you a question before you go ahead.

I'm having trouble understanding that this can properly be framed as a motion for summary judgment. How is this a claim or defense or part of a claim within Rule 56? It

seems to me that this is distinct from the, the type of claim or part thereof that is a proper subject of a Rule 56 motion.

MS. BIERSTEIN: Well, Your Honor, as you know, Rule 56 applies not only to a claim or defense, but a part of a claim or defense.

And here it is an element of our claim. One of the ways for us to prove nuisance and to prove their liability for the nuisance, one of the avenues for that -- and we've separately briefed this to Your Honor -- is to show that the defendants behaved unlawfully. So, it -- so what constitutes unlawful conduct in this context is an element of our claim.

And, so, the reason we've styled this as summary judgment is because it is an element -- you know, because, for example, this question of their failure to ship. Is it an element of our claim that they shipped when, when they had suspicious orders or is that not an element of our claim?

What Your Honor would be deciding is this piece of our claim and whether that's an element of the claim. And because it's a pure legal issue -- and this I know we, we -- this is addressed in our brief.

Because it's a pure legal issue, courts have found that part of a claim, the part of the claim that defines what's

the governing law is appropriate for summary judgment because it is a part -- that part of the claim. It's not, for example, an evidentiary issue, what's going to come in at the trial, what's not. It's what is the legal framework. And that is an element of our claim.

The other point I wanted to make, Your Honor, if that, if that has addressed that issue, is the defendants say that the proposed rule-making in 2020 is a changed circumstance from Judge Polster's ruling.

And if we can show Slide 5 -- I think we've got the slides working. So if we can show Slide 5, I want to talk a little bit about the proposed rule-making because the proposed rule-making did not affect this no-shipping duty.

What the proposed rule-making did was to give distributors options about the timing of reporting and due diligence. And it gave them the option to hold off on their reporting. And if they could investigate and clear the order fast enough, they would never have to report it.

What it did not do is change the no-shipping duty. And how do we know that? We know that because the DEA said that. They said it in the notice of proposed rule-making in the language I've put up on the slide where you see, "Identifying and reporting suspicious orders of controlled substances (and refusing to distribute based on such orders), has always been, and remains, the responsibility of

the DEA registrant."

So that key language, first of all, "refusing to distribute" and then those keywords "has always been."

So this is not new. This is not a changed rule. This is the DEA saying we're going to make your reporting life easier, but we are not changing the no-shipping duty which has always been your responsibility.

And, in fact, Your Honor, if you look at the proposed rule, both prongs of the rule, the two options that distributors now have, both prongs involve no shipping. The only thing that's changed is the timing of reporting.

And the DEA in order to remove any doubt that this no-shipping was new specifically said it has always been the responsibility. So the notion that there is anything new here I think is, is simply untenable.

And the reason for that, Your Honor, if we go back to the C.F.R., to the regulation -- and this would be Slide 4 if we can get that up -- because the C.F.R. puts an affirmative obligation on distributors, on all registrants to provide effective controls against diversion.

Now, the defendants like to say, and they said in their brief, that this isn't really an obligation on the registrants. This is for the DEA to use in deciding how to give out registrations.

Well, that's simply not true. That may be true in the

statute. But this regulation is absolutely clear that it is a, it is a directive to registrants. The term is "registrants" and the verb is "shall." This is what they must do. They must provide effective control to guard against diversion of controlled substances.

And our entire point -- and this is why I'm going to be able to wrap it up in about 30 seconds. Our entire point here -- and this was Judge Polster's point -- is that controls against diversions cannot be effective if a distributor can ship controlled substances when it knows the order is suspicious and has done nothing to investigate and clear up the suspicion or the questions or whatever you want to call them.

What would be the point of making them identify them if they're going to send the drugs anyway? That is not an effective control. That is what Judge Polster recognized that in order for controls to be effective, distributors must investigate and clear, if possible, the questionable orders before they ship them out.

That is a legal question. How it applies, which orders it applies to, whether they violated it, those are different questions. But this issue is: Does this regulation that I showed Your Honor entail an obligation to halt shipments pending due diligence we believe is a legal question suitable for summary judgment on which courts, including

Judge Polster and the D.C. Circuit and the DEA, have repeatedly recognized that -- and Congress recognized it in the SUPPORT Act.

And that's in our brief, so I'm not going to go through that again. But they recognized a pre-existing duty to stop suspicious orders.

So I think that would be the reason to rule on it and that's why we think it's clear that the duty exists.

THE COURT: Okay.

Mr. Farrell, were you done?

MR. FARRELL: Yes, sir, unless you have anything specific for me.

THE COURT: Okay. Let's hear from the other side on this.

MR. HESTER: Thank you, Your Honor.

First, I wanted to go back to the procedural point. We've talked previously about law of the case and why that doesn't apply.

It's also clear this is not properly a Rule 56 motion because it does not resolve a claim or defense or part of a claim or defense. The plaintiffs' argument that this is going to determine the legal framework for their motion, or for their position at trial, that's not a proper Rule 56 motion.

Of course, Rule 56 can be appropriate to resolve issues

that bar statutory construction. But that only applies if the legal question resolves a claim or a part of a claim. And here they can't make that argument.

And the reason is that the existence of a legal duty is not even an element of a claim for public nuisance. And a violation of a legal duty is neither necessary nor sufficient to establish a public nuisance. And that's well stated in the Restatement (Second) of Torts at Section 821B which says a violation of law is, quote, not conclusive.

So the plaintiffs aren't able to come forward and even argue today that this would resolve a part of their claim. They're asking the Court to set a, quote, legal framework which is something different from a Rule 56 motion.

But, in addition, I want to go back again to this point about why it's unnecessary in the setting of a bench trial for the Court to make this ruling now because even assuming a no-ship duty, the plaintiffs would still need to prove when it was in effect, how it applied at different points in time, and whether the defendants violated it. So the Court's going to need to hear evidence --

THE COURT: Would it make any difference on this point if this were a negligence action instead of a nuisance action? Would the, would the argument that this was a claim or part of a claim have more merit if this were a negligence case?

MR. HESTER: Well, perhaps, Your Honor. I haven't gone back recently to look at the law of negligence. But I suppose if, if the argument were there's negligence because of a violation of a statute that that could be an argument that it establishes a part of the claim. But here the public nuisance claim is not an element of their claim.

So -- but, but -- so I think the Court does not need to reach the merits here of whether there is a no-ship duty. But let me just speak to it quickly because I think it illustrates exactly why it's premature to be issuing a legal ruling at this stage before the Court has heard any evidence.

I think the plaintiffs acknowledge that the regulations do not specifically include a no-ship duty. There's nothing in the regulations that says a registrant shall not ship an order that it has reported as suspicious.

So we're in a setting where the plaintiffs are asking us to read into the regulations a requirement that the agency did not provide for.

And it's notable, Your Honor, that the regulations specifically define suspicious orders. They specifically require the registrant to inform DEA of suspicious orders. But the regulations omit and do not include the requirement not to ship.

And the DEA itself in the regulations states that these

are the regulations that establish the, quote, standards that are, quote, necessary to prevent diversion. Yet, DEA did not include a no-ship requirement for suspicious orders in those standards.

And it's notable here that plaintiffs are saying, well, of course, there must be a no-ship requirement if there's a, if there's an obligation to have effective controls against diversion. But the DEA did not itself make that judgment. It's not in the rules.

And we can see also in the rules the DEA has other no-ship requirements in the regulations. It prohibits, for instance, any shipment of controlled substances as samples. But it does not prohibit the shipping of suspicious orders.

So, in short, we have a detailed extensive regulatory scheme that addresses the handling of controlled substances and the reporting of them, but no regulation stating that a suspicious order cannot be shipped.

So under standard principles of construction, a Court cannot and should not read into those regulations a rule that the agency omitted because the Court would in effect be second-guessing the agency's judgment.

And the fact that the current rules don't include a no-ship requirement is demonstrated, in our view, by the fact of the DEA's recent rule-making to add a no-ship requirement. If the, if the plaintiffs were right that this

has always been in the rules, there's no reason for the agency to be adding it now.

But that gets to the heart of it, Your Honor. The plaintiffs ultimately are not able to point to something in the rules that establishes a no-ship requirement.

What they're doing is arguing (video inaudible) for which it applied. And I think you've heard this argument today. When the rules say you need to provide effective controls against diversion, necessarily that means you can't ship a suspicious order. And they, they logically get to that conclusion through inference. It's not stated in the rules.

But this is the fundamental legal and logical flaw in the plaintiffs' argument and in Judge Polster's order because you have here, first of all, the controlling point of law that a court can't read a new regulatory obligation into a detailed set of regulations that omit any such obligation. That's for the agency to decide.

But even if we put aside that threshold point, a requirement not to ship suspicious orders can't be inferred from the statutory or regulatory requirement to prevent diversion.

And the reason why, Your Honor, is because these are two different principles.

The regulations define suspicious orders as orders of

unusual size deviating substantially from a normal pattern or of unusual frequency.

And the evidence that the Court is going to hear will demonstrate that the vast majority of orders that might be suspicious within that definition are not, in fact, likely to be diverted.

So the inference that the plaintiffs are asking you to draw as a matter of logic is defeated by the evidence. And the evidence is going to show that the vast majority of suspicious orders are entirely appropriate and not likely to be diverted.

And it's important to highlight the plaintiffs are not alleging a failure to block orders likely to be diverted. They're alleging a duty to block each and every suspicious order.

Well, the Court should hear evidence on that difference, on the difference between a suspicious order and one that's likely to be diverted. And I think the evidence will show very clearly those are different.

And it goes to this question of drawing an inference from an absence of something in the regulations inferring a duty that isn't stated by the agency without hearing any evidence.

And, in particular, the evidence is going to show why suspicious orders are different from orders likely to be

diverted. And in our view, Your Honor, the Court should hear that testimony before it rules on the scope of these purported duties under the CSA.

And I, I also wanted to highlight, Your Honor, whether or not -- I, I think that should resolve it, in our view, that the Court should hear evidence. It's not properly a Rule 56 motion. It's not properly law of the case. And the evidence is going to inform the legal duty that the plaintiffs are asking the Court to find.

But, in any event, at a minimum, there's disputed questions, issues of fact around the existence of this duty before 2008. And the plaintiffs, as the Court heard, are arguing that the, that the duty is inherent in the regulations. But that is a disputed point because *Masters*, the case that Mr. Farrell referred to, D.C. Circuit decision from 2017, expressly stated the DEA, quote, first articulated, first articulated a no-ship requirement in *Southwood* in 2007.

And there's also a decision we cite in our brief, *United States* vs. *$463,000*, quite a case name, where the Court found that DEA announced on September 11th, 2007, a, quote, new interpretation of the suspicious order regulations.

There's also going to be testimony of DEA witnesses that the no-ship policy changed around 2008. And that

evidence is set out at Pages 16 to 19 of our opposition brief.

The evidence reflects the DEA first asked distributors to start blocking suspicious orders during an industry conference in late 2007. And the evidence will also reflect that before then, before late 2007, DEA wanted distributors to report suspicious orders and DEA would investigate them, not the distributors.

So the evidence reflects the DEA, in fact, approved programs before 2007 where distributors reported and then shipped suspicious orders.

And, so, there's no basis to find this duty as a matter of law and undisputed facts before 2008. In fact, the plaintiffs themselves say that the no-ship requirement is an interpretive rule that, quote, simply states what the administrative agency thinks the statute means. That's Page 10 of their brief.

So the rule they're asking the Court to find in their own phraseology is what the administrative agency thinks.

Well, the Court should hear evidence on what the administrative agency thinks before it decides on that duty even under the plaintiffs' own phrasing of the issue.

And in our brief, Page 17 to 18, we demonstrate this was a very significant change in policy that occurred at the end of 2007, and that before mid 2007, DEA recognized that

distributors were shipping orders after they reported them as suspicious.

So it all goes back to where we began, I think, on the procedural point. There's -- it's not law of the case. It's not Rule 56. And there's good reasons for the Court to hear this evidence on the evolution of this purported policy before it decides on the question of a legal duty.

And we would submit, Your Honor, that those factual points on the difference between a suspicious order and an order likely to be diverted will be very important to the Court's ultimate judgment about whether it can or should infer a duty that's not stated in the regulations.

So we think procedurally it's not proper what the plaintiffs are asking the Court to do, but we also think as a matter of the Court's discretion, there's very good reasons to wait on this and hear evidence in a bench trial before the Court makes such a ruling.

THE COURT: Okay. This is the plaintiffs' motion. We've got a few minutes here, so I'll give the plaintiffs the last word if you want to say anything but we need to make it quick because I've got to get out of here.

MS. BIERSTEIN: Judge, I had a couple quick rebuttal points.

I wanted to say, first of all, that on this question of putting in evidence on the difference between suspicious

orders and orders likely to be diverted, our point is that you need to do due diligence to know the difference.

We're not saying you can never ship a suspicious order. We're saying you have to do the due diligence to figure out the difference between the suspicious orders and the ones that are actually likely to be diverted.

The evidence they want to put on to show you that there's a difference is not what they did at the time. They made no investigation. The evidence isn't relevant because you would have to show that they were considering that kind of evidence when they did what they did. And they didn't do that.

Our, our -- the legal ruling we're asking for isn't that none of these orders can be shipped. It's that none of these orders can be shipped until you do the due diligence that takes into account exactly the facts that they would, you know, want to convince Your Honor that some of those orders are not likely to be diverted, yes, but you have to do the due diligence to know that.

Second of all, the DEA has set this rule. We're not asking the Court to read into the regulations something that DEA has never said. They've said it repeatedly. As I showed you already, they said it most recently in 2020.

Finally, I want to say that in terms of evidence about the administrative agencies, I would (video inaudible)

rules. What you would be looking at are the DEA's official pronouncements, not what a particular agent that they're going to put on the stand is going to tell you, well, this is what we thought at the DEA. That's not how the Court determines what -- how the DEA interpreted its rules.

And, so, I think what we've seen is not only how they interpret the rules, but they've told us in 2020 what the rule always was. And they said it in an official notice of rule-making in the Federal Register.

And I think that the Court does not need factual evidence to consider how the DEA has construed its own regulation. And I will stop and have nothing more to add.

THE COURT: Okay. Thank you, counsel, very much. And we'll leave it at that.

(Proceedings concluded at 10:28 a.m.)

I, Lisa A. Cook, Official Reporter of the United States District Court for the Southern District of West Virginia, do hereby certify that the foregoing is a true and correct transcript, to the best of my ability, from the record of proceedings in the above-entitled matter.

s\Lisa A. Cook — February 11, 2021

Reporter — Date